DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
95037

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Warning Letter

FLA-04-43

September 29, 2004

Lloyd Slabach, President and Owner
Timothy Romero, Vice President and Owner
F. H. G. Corporation
Integrity Nutraceuticals International
201 Field End Street, Suite A
Sarasota, Florida 34240

Dear Mr. Romero and Mr. Slabach:

This letter concerns your products "4-Androstenedione," "Cinnulin PF™," "Gamma Oryzanol," "Chitosan," "5-Methyl-7-Methoxyisoflavone," and "Grape Seed Extract." FDA inspections on April 21 and 26, 2004, and July 23, 2004, documented that you stated your firm is holding a shipment of 4-Androstenedione capsules. According to an affidavit signed by Timothy Romero on July 23, 2004, and accompanying documents provided by Mr. Romero, these 4-Androstenedione capsules were ordered from your firm by [redacted] a firm in Pennsylvania, and you consider them to be dietary supplements.

The term "dietary supplement" is defined in 21 U.S.C. 321(ff) [section 201(ff) of the Federal Food, Drug, and Cosmetic Act (the Act)]. Given that you have represented your product 4-Androstenedione as a dietary supplement, we assume you have a basis to conclude that androstenedione (also referred to as 4-androstenedione or 5-androstene-3,17-dione, among other names) is a "dietary ingredient" under 21 U.S.C. 321(ff)(1). Assuming that androstenedione is a "dietary ingredient," it would also be a "new dietary ingredient" for which a notification is required under 21 U.S.C. 350b(a)(2) and 21 CFR 190.6.

Under 21 U.S.C. 350b, a dietary supplement that contains a new dietary ingredient (i.e., a dietary ingredient not marketed in the United States before October 15, 1994) shall be deemed adulterated under 21 U.S.C. 342(f) unless it meets one of two requirements:

(1) The dietary supplement contains only dietary ingredients that have been present in the food supply as an article used for food in a form in which the food has not been chemically altered; or

(2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides FDA with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

FDA is not aware of any information demonstrating that androstenedione was lawfully marketed as a dietary ingredient in the United States before October 15, 1994. Nor is FDA aware of any information demonstrating that this ingredient has been present in the food supply as an article used for food in a form in which the food has not been chemically altered. In the absence of such information, androstenedione is subject to the notification requirement for a new dietary ingredient in 21 U.S.C. 350b(a)(2) and 21 CFR 190.6. Because you have not submitted the required notification, your product is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a).

Even if the required notification had been submitted, based on what we know now, we know of no evidence that would establish that your product is not adulterated. In the absence of a history of use or other evidence of safety establishing that androstenedione, when used under the conditions recommended or suggested in the labeling of your product, will reasonably be expected to be safe, a product containing androstenedione is adulterated under 21 U.S.C. 342(f)(1)(B) and 350b(a) as a dietary supplement that contains a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury. Introduction of such a product into interstate commerce is prohibited under 21 U.S.C. 331(a) and (v). FDA is aware of no history of use or other evidence of safety establishing that androstenedione will reasonably be expected to be safe as a dietary ingredient. In the absence of such history of use or other evidence, your product would be considered adulterated even if you had submitted a notification.

We request that you take prompt action to correct these and any other violations associated with "4-Androstenedione" and any other products marketed by your firm that contain androstenedione. We note that the list of prohormone products on your website (http://www.integritynut.com/prohormones.htm) includes 4-Androstenedione, and our inspections documented that your firm orders and receives 4-androstene-3,17-dione. This Warning Letter applies to these

ingredients and to dietary supplements that contain these ingredients. We also remind you that the new dietary ingredient notification requirement applies to all dietary supplements that contain new dietary ingredients that have not been present in the food supply as articles used for food in a form in which the food has not been chemically altered. To date, your firm has not submitted any such notifications.

We have also reviewed your web site at the Internet address: http://www.integritynut.com. Based on claims that appear on this website, we have determined that the products "Cinnulin PF™," "Gamma Oryzanol," "Chitosan," "5-Methyl-7-Methoxyisoflavone," and "Grape Seed Extract" are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(g)(1)(B)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act and may subject you or the products to regulatory action without further notice.

Examples of some of the claims observed on your web site include:

Cinnulin PF™
"[C]ontains insulin potentiating fractions that may be beneficial for type II diabetes, obesity, ... and various other ailments possibly developed by insulin resistance."

Gamma Oryzanol
"Gamma oryzanol is useful for ... reducing cholesterol levels...."

Chitosan
"[C]hitosan also inhibits bad cholesterol and boosts good cholesterol, promotes healing of ulcers and lesions, ... helps control high blood pressure, and helps reduce blood levels of uric acid which causes gout."

5-Methyl-7- Methoxyisoflavone
"[B]eneficial for ... lowered cholesterol."

Grape Seed Extract
"The active constituent is oligomeric proanthocyanidins, also known as OPCs. ... OPCs also act as a natural histamine and can be helpful treating allergies, asthma, bronchitis, arthritis, muscle tissue injuries and ulcers."

Cinnulin PF™, Chitosan, Gamma Oryzanol, 5-Methyl-7- Methoxyisoflavone, and Grape Seed Extract are misbranded section 502(f)(1) of the Act, in that they fail to bear adequate directions for use.

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that all products marketed by your firm and all labeling for such products comply with the Act and its implementing regulations.

We acknowledge receipt of Mr. Romero's letter dated April 27, 2004 submitted to this office in response to our inspection. This letter does not alleviate our concerns with regard to the inspectional findings in that it does not provide any information about permanent corrective actions to your firm's operations, if any, that you have implemented.

Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) an explanation of each step being taken to identify and make corrections to any problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Shari H. Shambaugh, Compliance Officer, at the above address.

Sincerely,

Emma R. Singleton
Director, Florida District